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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,441	06/04/2002	Alan Leedham Hart	JAMES60.001APC	3224

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EXAMINER

SHEN, BIN

ART UNIT	PAPER NUMBER
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1655

DATE MAILED: 05/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/069,441

Applicant(s)

HART ET AL.

Examiner

Bin Shen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/17/2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1--31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u> </u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on November 17, 2004 has been entered.

Specification

2. The abstract of the disclosure is objected to because of the usage of the legal phraseology "said" in line 2. Applicant is reminded of the proper language and format for an abstract of the disclosure. The form and legal phraseology often used in patent claims, such as "said," should be avoided.

3. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). In claim 10 the simultaneous performance of steps (b) and (c) according to claim 1 lacks the proper antecedent basis. The closest potential support for the claimed subject matter is on page 8, line 19 of the descriptive portion of the specification, where it clearly states, "After homogenization the enzyme solution was added". However, this does not actually provide support for the claim, which dictates to simultaneously adding hydrolyzing enzyme while forming homogenous slurry. Thus fail to provide proper

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support/antecedent basis for claim 10. Correction of the following is required: appropriate amendment to the description to provide clear support or antecedent basis for the term appearing in the claim.

Claim Objections

4. Claims 3 and 24 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 3 and 24 recite the limitation "wherein said complex carbohydrate is selected from the group consisting of glycogen" in line 2 of the claims, fail to further limit the subject matter of a previous claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-31 are rejected under 35 U.S.C. 112, second paragraph. Claim 1 is vague and indefinite since it claims "complex carbohydrates" in the preamble and the claim ends with a specific carbohydrates "glucose". It would be clearer if applicant started and ended with the same sugar. Also it appears in Claim 1, line 1 "an amount of" should precede "complex carbohydrates". In claim 3, glycogen and lactate are chosen as the sugar. It is confusing to use these sugars as the "complex carbohydrates" since Claim 1 ends with glucose. Clearly glucose

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is not glycogen or lactate. Claims 4 and 5 recite the limitation "solvent" in line 2 of the claims. There is no antecedent basis for this limitation in the claims. Claims 16, 17, 27 and 28 recite the limitation "glycogen measurement" in line 2 of the claims. There is no antecedent basis for this limitation in the claims. Further, the use of "effected" in claims 16, 17, 27, 28 is not understood. It appears that applicant should use "performed". Claims 21-23, 29-31 are rendered vague and indefinite by the phrase "A method of measuring ultimate pH comprising"-e.g., it is unclear what ultimate pH the method is measuring.

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under USC 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 3-8, 18, 19, 21, 22, 25, 26, 29 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Rink et al. (USPN 5814600).

The Rink et al. patent '600 teaches measurement of glucose in mammalian tissue (including skeletal muscle-see example 1, and liver) (see column 12, line 21-45). Specifically it teaches the extraction of mammal tissue, homogenization of the tissue in

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water based buffer with standard ionic condition (read as forming a slurry), hydrolysis of glycogen with amyloglucosidase, and assaying for glucose in an analyzer using glucose oxidase immobilized enzyme chemistry. The incubation is carried out at 23°C (about room temperature), and the method is performed post-mortem. Therefore, the reference is deemed to anticipate the instant claims above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rink et al. (USPN 5814600), in view of EP 0086108A2, and further in view of Calder et al. (International Journal of Biochemistry (1990) 22 (8) 847-856) and Heller et al. (USPN 5262305).

The Rink et al. patent '600 teaches what is above.

The Rink et al. patent '600 does not disclose the measurement of lactate, the use of biosensor, and that the method is performed in less than 30 minutes.

EP teaches the importance of rapidly measuring lactate in skeletal muscles as an indication of certain critical features in mammals (see page 1 lines 4-6). EP discloses a rapid method of measuring lactic acid in a liquid (page 4 line 14) in 40

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seconds (page 5 line 20) with enzyme-coupled electrodes (see page 4 of EP).

Calder et al. teach the rapid degradation of skeletal muscle glycogen and changes in the level of glucose and lactate in the first 2 hrs post mortem (see Table 4 on page 853, Table 1 on page 849 and Figs 2 and 3 on page 850). By 20 minute post mortem, most of the rat muscle glycogen is degraded (page 853 line 4).

Heller et al. patent '305 teaches an interferant-eliminating biosensor with an insulating barrier layer between the catalyst (i.e., hydrolyzing enzyme) and sensing layer (i.e., glucose oxidase/lactate oxidase-see column 1 line 18-24, line 54-64, and claim 6 on column 12 line 31).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the glucose measurement method taught by Rink et al. with the measurement of lactate taught by EP since EP teaches the importance of rapidly measuring lactate in skeletal muscles and Rink also measures muscle glycogen. One of the ordinary skill in the art at the time the invention was made would have been motivated to perform the method of measuring glucose (as taught by Rink) and lactate (as taught by Rink et al. and EP) within 30 minute post mortem before glycogen degradation because Calder et al. teaches the rapid degradation of muscle glycogen after 20 minute post mortem. Rink teaches the use of an analyzer (biosensor). Heller shows a biosensor capable of specifically sensing an analyte to be detected and an interferant-eliminating layer containing catalyst. Thus, it would have been obvious to use a biosensor (taught by Heller) in Rink that contains hydrolyzing enzyme (in the interferant-eliminating layer) and glucose/lactate oxidase

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(in the sensing layer) to measure glucose and lactate together, the person of ordinary skill in the art would have had a reasonable expectation of success to achieve the goal of finishing the measurement of glucose and lactate within 30 minutes post mortem because EP teaches the successful measurement of lactate level in about 40 seconds (see above), and the measurement of glucose and lactate will be a single step method using interferant-eliminating biosensor (taught by Heller).

Regarding claims 23 and 31, directed to different types of muscles used in the claimed method, the use of skeletal muscles (according to "Merriam Webster's Medical Desk Dictionary": *gluteus medius*, and *semitendinosus* are types of skeletal muscles) to measure glucose and lactate has long been known in the art as shown by Rink and Calder et al. (see above). Since Rink and Calder teaches the measurements of glucose and lactate in skeletal muscles, it would encompass claims 23 and 31.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

8. No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Certain papers related to this application may be submitted

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to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is 571-273-8300. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well

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as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Bin Shen whose telephone number is (571) 272-9040. The examiner can normally be reached on Monday through Friday, from about 9:00 AM to about 5:30 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to her office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Terry McKelvey can be reached at (571) 272-0775.

B Shen

Patent Examiner
Art Unit 1655
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**MICHAEL MELLER
PRIMARY EXAMINER**